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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,521	06/26/2003	Stefan Schafer	DEAV2002/0044US NP	6023

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EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/607,521

**Applicant(s)**

SCHAFFER ET AL.

**Examiner**

Raymond J Henley III

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/12/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**CLAIMS 1-30 ARE PRESENTED FOR EXAMINATION**

Applicants' Information Disclosure Statement filed July 30, 2003 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08A (2 pages), the cited references have been considered.

***Claim Rejection - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a disease amenable to treatment with an a compound that both inhibits angiotensin converting enzyme and neutral endopeptidase, does not reasonably provide enablement for the treatment of "a disease" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The present objective of treating "a disease" reads on a panacea, i.e., treating a patient for any and all purposes, and the art currently is unaware of any single agent, or combination of agents that could be used for the treatment of any and all disease states.

In order to overcome this rejection, applicant may wish to consider amending claim 1 to read, in part, ---A method of inhibiting both angiotensin converting enzyme and neutral endopeptidase for the treatment of a disease amenable to treatment with an a compound that both inhibits angiotensin converting enzyme and neutral endopeptidase which comprises...---.

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A similar amendment should be made to the appropriate section of claim 30.

***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 11-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flynn et al. (U.S. Patent No. 5,430,145, cited by Applicants) who teach methods for treating renal diseases, i.e., nephropathies, arteriosclerosis and vascular myointimal thickening following balloon injury, i.e., vascular endothelial

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dysfunction, (col. 2, lines 13, 44 and 49) which comprises the administration of the presently claimed compounds (col. 3, line 1 – col. 4, line 68 as well as the Certificate of Correction Sheets) as well as method for the preparation of pharmaceutical compositions which comprise the presently claimed compounds by mixing such compounds with one or more pharmaceutically acceptable excipients (col. 70, line 14 – col. 71, line 17).

Should the compounds not be anticipated, they would have nevertheless been obvious from the teachings at col. 3, line 1 – col. 4, line 68 as well as the Certificate of Correction sheets where the basic structure of the present compounds as well as the moieties necessary to form the specifically claimed compounds are provided for.

While Flynn et al. are silent as to the activity of the compounds as neutral peptidase inhibitors, such would be inherent in the prior art because the same compounds are being administered to the same patients for the same therapeutic purposes.

***Comments Regarding Claims 4 and 6-9***

Claims 4 and 6-9 are directed to certain disease that the Examiner believes would have been obvious in view of Moskowitz (U.S. Patent Application Publication 2003/0040509). That is, because Moskowitz teaches that angiotensin converting enzyme inhibitors could be used to treat diabetic nephropathy, diabetic neuropathy, diabetic retinopathy, myocardial infarction and cataracts (page 2, Table 1 and page 14, col. 2, claim 16), while the presently claimed compounds were known from Flynn et al. (above) to possess, in part, angiotensin converting enzyme inhibitory activity.

The present claims, however, would not be properly rejected because claim 1 (and claim 29) is directed to the inhibition of both angiotensin converting enzyme and neutral endopeptidase

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in a patient in need thereof. The objective of inhibiting neutral endopeptidase is not taught by either Moskowitz or Flynn et al. and one cannot conclude that such an objective would be inherent when considering the subject matter of claims 4 and 6-9. This is so because for inherency, as set forth in MPEP 2112:

‘To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. **Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**’ ” In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)’.

That is, by saying that it would have been obvious to treat the conditions of claims 4 and 6-9 with the claimed compounds by taking the teachings of Flynn et al. in view of Moskowitz, it would be equivalent to saying that it would have been probable or possible for the skilled artisan to have used the presently claimed compounds for the treatment of the diseases of claims 4 and 6-9. Such a condition of probability or possibility dictates against a finding of inherency. Accordingly, claims 4 and 6-9 are not subject to the above rejection.

#### ***Comments Regarding Claims 5 and 10***

Claims 5 and 10 are free of the prior art because the prior art fails to teach the treatment of insulin resistance or diabetic cardiomyopathy with the presently claimed compounds.


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

June 2, 2004